K022976

JAN 16 2003

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§ 807.92.

Submitter's Name:

Richard M. Vaught
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P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: September 4, 2002

Name of Product: Dade Behring Stratus® CS D-dimer method; includes separately supplied TestPak (assay) and DilPak (diluent)

FDA Classification Name: Fibrinogen/fibrin degradation products assay

Predicate Device: bioMerieux Vitek VIDAS® D-dimer Assay (K973819)

Device Description: The Dade Behring Stratus® CS D-dimer TestPak method is an enzyme-linked fluorescent immunoassay that consists of a five(5)-well, plastic cartridge (TestPak) designed for use only on the Dade Behring Stratus® CS fluorometric analyzer. Within the TestPak cartridge is a small square of embedded glass fiber paper. Reagents and sample are added through an opening onto the glass fiber paper. Following incubation, the enzyme-labeled antibody and the bound D-dimer fraction react. The enzymatic rate of the bound fraction increases with the concentration of the D-dimer in the sample and is measured via fluorescence. Dilutions, if needed, may be accomplished via utilization of the Stratus®CS DilPak

(diluent) cartridges. All data analysis functions are performed automatically by the analyzer.

Intended Use:

The Dade Behring Stratus® CS D-dimer method is an *in vitro* diagnostic test for the quantitative measurement of cross-linked fibrin degradation products (D-dimer) in human citrated or heparinized plasma.

Comparison to Predicate Device:

The Stratus® CS D-dimer method is substantially equivalent in technological design and intended use to other D-dimer assays such as the bioMerieux Vitek VIDAS® D-dimer assay (K973819). A comparison of the features of these products is provided below:

Feature	Dade Behring Stratus® CS D-dimer Method	bioMerieux Vitek VIDAS® D-dimer Assay
Intended Use:	*in vitro* use	*in vitro* use
Technology:	Automated Fluorescent immunoassay; 450nm Alkaline phosphatase = eonjugate 4-methylumbelliferyl phosphate = substrate	Automated Fluorescent immunoassay; 450 nm Alkaline phosphatase = conjugate 4-methylumbelliferyl phosphate = substrate
Sample:	whole blood/plasma	plasma
Sample volume:	75 uL	200 uL
Assay range:	6 - 5000 ng/mL	45 - 1000 ng/mL
Calibration:	Calibration curve updated for each lot, using one level (triplicate) and every 60 days, thereafter. After calibration update at completion of each test, recovered values are calculated from stored calibration coefficients.	One point calibrator tested (duplicate) with each lot initially and every 14 days, thereafter.

Comments on Substantial Equivalence:

Split sample comparison with citrated human plasma samples between the Stratus® D-dimer method and the VIDAS® D-dimer (DD) assay gave a correlation coefficient of 0.923, a slope of 0.995 and an intercept of 159 ng/mL. In this study, clinical patient

samples (n = 123) were tested at Dade Behring (Glasgow, Delaware) and ranged from 79 ng/mL to 5689 ng/mL as tested on the VIDAS® D-dimer assay.

Conclusion:

The Dade Behring Stratus® CS D-dimer (DDMR) method and the bioMerieux Vitek VIDAS® D-dimer (DD) assay are substantially equivalent in intended use, technological design and specific performance characteristics, including split sample comparison results as noted above.

RMVaught

Richard M. Vaught
Regulatory Affairs and Compliance Manager
September 4, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
Glasgow Site, Bldg. 500, Box 514
P.O. Box 6101
Newark, Delaware 19714-6101

JAN 16 2003

Re: k022976
Trade/Device Name: Stratus® CS D-dimer (DDMR) Method
Regulation Number: 21 CFR § 864.7320
Regulation Name: Fibrin Degradation Products
Regulatory Class: II
Product Code: DAP
Dated: December 18, 2002
Received: December 20, 2002

Dear Mr. Vaught:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Device Name: K022976

Stratus® CS D-dimer (DDMR) Method

Indications for Use:

The Dade Behring Stratus® CS D-dimer method is an *in vitro* diagnostic test intended for use with the Stratus® CS fluorometric analyzer for the determination of cross-linked fibrin degradation products (D-dimer) in plasma.

R M Vaught

Richard M. Vaught
Regulatory Affairs and Compliance Manager

September 4, 2002

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jayashree Bantia

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022976

Prescription Use ✓ **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)